

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION
TO EXCLUDE CERTAIN GENERAL OPINIONS OF MARC TOGLIA, M.D.**

Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson (collectively “Ethicon”) submit this response in opposition to Plaintiffs’ notice of adoption of its prior motion to exclude general opinions of Marc Toglia, M.D. (Doc. 2792, 2028).

INTRODUCTION

Dr. Toglia is an internationally recognized expert in the field of urogynecology, currently serving as the Chief of Female Pelvic Medicine and Reconstructive Surgery for the Main Line Health System in Philadelphia. Ex. B to Pl’s motion, TVT Report at 1; Ex. A hereto, Toglia CV. He is double board certified in Female Pelvic Medicine and Reconstructive Surgery, and Obstetrics and Gynecology. Pl’s Ex. B, TVT Report at 1. Dr. Toglia is an editor for two premier urogynecology medical journals, Female Pelvic Medicine & Reconstructive Surgery and the International Urogynecology Journal, and serves active leadership roles in the American Urogynecologic Society and the Society for Gynecologic Surgeons. *Id.* Over the course of his career, he has performed thousands of gynecologic surgeries, specifically female pelvic floor reconstruction, including native tissue repair, biological graft and synthetic mesh augmented repairs. *Id.* at 2.

Dr. Toglia began using the TVT in 1999, continues to use the product, and has performed thousands of TVT (and related SUI device) procedures as well as pelvic organ prolapse procedures. Ex. B hereto, 3/24/16 Toglia Dep. 52:22-53:11; Ex. C hereto, 10/02/15 Toglia Dep. 58:16-19, 64:12-14. His current practice focuses exclusively on the care of women who have urinary incontinence and pelvic floor disorders. *Id.* at 13:2-7. Dr. Toglia's decades of clinical work are supplemented by his direct involvement in research, publication and teaching. Pl's Ex. B, TVT Report at 1-2. He has authored a randomized clinical trial that compared the retropubic TVT with a newer sling device. He also authored a retrospective study that examined complications arising out of the use of sutures in native tissue repairs for vaginal reconstruction. *Id.* at 2; Ex. C hereto, 10/02/15 Toglia Dep. 77:4-7, 79:8-80:11 (discussing involvement in study comparing the TVT to TVT-Secur). These studies have been presented at both national and international scientific meetings. Pl's Ex. B, TVT Report at 2. He has taught numerous physicians, including gynecologists, urologists and residents surgical procedures such as implantation of the TVT sling over the past two decades. *Id.* at 2; Ex. C hereto, 10/02/15 Toglia Dep. at 217:24-218:3. This includes serving as faculty in a wide range of professional educational activities, including invited lectures, cadaver labs, as well as proctoring and preceptorships. TVT Report at 2.

As set forth below, Plaintiffs' challenges to Dr. Toglia's opinions lack merit.

ARGUMENT

- I. Dr. Toglia is well qualified to provide his opinions, and his opinions are supported by reliable methodology.**
 - A. Dr. Toglia's clinical experience is a proper basis for his opinions and is reinforced by peer-reviewed literature and other scientific evidence.**

As set forth in the Introduction section above, Dr. Toglia is imminently qualified to provide expert opinions addressing the utility and safety of Ethicon's devices, and he has drawn on his clinical and research experience in formulating his opinions. Plaintiffs suggest that Dr. Toglia's opinions about the safety and efficacy of the devices at issue are unreliable and that his "own clinical experience is unsupported by factual evidence." Doc 2028 at 4.

Contrary to Plaintiffs' argument, Dr. Toglia's opinions are well supported by his decades of clinical experience. *See, e.g.*, Ex. C hereto, 10/02/15 Toglia Dep. at 151:22-152:9, 344:6-17. Further, contrary to Plaintiffs' argument, Dr. Toglia is not "relying solely or primarily on experience" (Doc. 2028, p. 5), but rather on experience and education combined with an extensive analysis of scientific evidence. In his expert reports, he described in detail reliable high level data and how it is consistent with his personal experience. *See, e.g.*, Pl's Ex. B, TTV Report at 17-22, 30-31. According to Dr. Toglia, he "reviewed the highest levels of evidence" that he could find. Ex. C hereto, 10/02/15 Toglia Dep. 36:12-39:15, 322:14-324:10. He relied upon the generally accepted Level of Evidence Chart to assess and categorize the potentially relevant evidence. *Id.* at 326:24-330:12 & Ex. 17 thereto (attached hereto as Ex. F). The Level 1 evidence included "randomized controlled trials, systematic reviews or meta-analysis," which provided a "tremendous amount of data." *Id.* at 323:6-10.¹ Additionally, he reviewed Level 2 data such as long-term registry studies and data from closed health systems, as well as societal guidelines and position statements. *Id.* at 323:15-22.

Dr. Toglia also reviewed documents provided by counsel, including internal Ethicon documents and the opinions of Plaintiffs' experts, as well as evidence relied upon by Plaintiffs' experts, such as animal studies, and hernia documents. *Id.* at 37:9-39:15, 324:1-15. As noted by

¹ As Dr. Toglia emphasized, the foundation of any systematic review, including the one he performed in reaching his opinions, is to start with the highest level of evidence. *Id.* at 327:12-16.

Dr. Toglia, the bulk of such evidence was “Level 5 data, that you really can’t draw any clinical inference or--- or application directly to” the devices. *Id.* at 324:5-10. Where the Level 5 evidence is incongruent with Level 1 evidence, the lower level evidence is significantly less useful. *Id.* at 327:11-22.

Plaintiffs focus their attack on the notion that Dr. Toglia could not verify with mathematical precision his understanding of his patients’ complication rates and follow-up rates. Ethicon acknowledges that, in its Wave 1 ruling, the Court excluded “Dr. Toglia’s opinions on complication rates and patient follow-up rates in his own practice,” finding that Dr. Toglia’s rates were unreliably based on his memory alone. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493666, at *3 (S.D. W. Va. Aug. 25, 2016). Ethicon respectfully suggests that Dr. Toglia’s opinions about these rates in his own practice are sufficiently reliable.

Indeed, Dr. Toglia has tracked his patients’ complication rates over time by “keep[ing] notes on the patients” and using spreadsheets. *Id.* at 336:2-15, 413:12-19. He also explained that in his hands, complication rates have been in the single digits, making it easy to recall when there are complications. *Id.* at 336:2-15. The rates he provided in his reports, and provides to his patients, are based on his “firsthand observations and tracking of complication rates over time.” *Id.* at 337:20-338:8. Thus, Ethicon respectfully requests that the Court allow Dr. Toglia to testify about such rates consistent with other decisions issued by the Court. *See Ex. D hereto, Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014) (“If Daubert required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions”); *Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015) (finding that expert’s inability to provide “exact statistics” about the outcome of his patients did

not render his personal experience opinions unreliable and that “such detail is not required under *Daubert* to opine as to ‘large-scale safety and efficacy of the Uphold device’); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same).

Alternatively, the Court, as it did in its Wave 1 ruling, should limit its exclusion of Dr. Toglia’s opinions to his statements about his own patients’ complication rates and patient follow-up rates.

B. Dr. Toglia does not intend to offer opinions about the FDA clearance process.

Citing one sentence in Dr. Toglia’s report in which he observes that Plaintiffs draw their cytotoxicity claims from testing submitted during the 510(k) process, Plaintiffs ask the Court to preclude Dr. Toglia from testifying about FDA regulatory issues. Pl’s Ex. B, TTV Report at 27. This is not an expert opinion at all, let alone an opinion regarding the 510(k) process itself, and is not subject to *Daubert* standards. Dr. Toglia does not intend to offer any opinions at trial regarding the FDA’s 510(k) clearance process.

C. The Court should allow Dr. Toglia to testify about polypropylene safety, durability and biocompatibility.

Despite Dr. Toglia’s aforementioned elite qualifications as a urogynecologist, Plaintiffs claim that he is not competent to testify about polypropylene safety, durability, biocompatibility, and similar issues. Doc. 2028, p. 7. Plaintiffs’ argument does not comport with Dr. Toglia’s experience or with this Court’s decisions.

Finding Plaintiffs’ challenge on these same issues in the Wave 1 cases to be “without merit,” the Court found that Dr. Toglia’s “extensive clinical and research experience qualifies Dr. Toglia to opine on mesh’s reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products.” *In re Ethicon*, 2016 WL 4493666, at *3. Indeed, Dr. Toglia is a materials expert with a special understanding of polymer medicine as it relates to his

subspecialty field, and his opinions are premised upon a thorough understanding of the interaction of living systems with permanent surgical implants, along with clinical observations from performing thousands of revision and removal procedures involving mesh. Ex. C hereto, 10/02/15 Toglia Dep. 144:7-15; *see also* Ex. B hereto, 3/24/15 Toglia Dep. 120:3-23, 256:10-257:23.

Dr. Toglia's experience in the field of biomaterials includes consulting regarding the development and design of implantable surgical mesh devices. Pl.'s Ex. B, TVT Report at 2. In fact, he was consulted on the original TVT Retropubic, Obturator and Secur devices, as well as products within the TVT Prolift family of products, and he had significant involvement in the design of the TVT-Exact product. Ex. C hereto, 10/02/15 Toglia Dep. 72:5-14, 74:4-24; Ex. B hereto, 3/24/15 Toglia Dep. 124:8-24. Further, Dr. Toglia was one of the surgeons who participated in the design validation of the GYNEMESH® M mesh, assessing the suitability, safety and efficacy and adequacy of the design. Ex. C hereto, 10/02/15 Toglia Dep. 339:3-9. He has also consulted on the design and the analysis of other prototype procedures. Dr. Toglia's education, experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its alleged degradation and other biomaterial properties.

In addition to challenging Dr. Toglia's qualification to opine regarding biomaterial properties, Plaintiffs wrongly criticize Dr. Toglia's methodology supporting his opinion that the TVT mesh is a lightweight mesh, arguing that he has failed to demonstrate a "basic understanding" of the concept. Doc. 2028, p. 7. However, it is Plaintiffs who fail to understand Dr. Toglia's testimony and opinion. As Dr. Toglia explained, "weight of mesh is dependent upon the volume of surface area." Ex. C hereto, 10/02/15 Toglia Dep. 55:16-18; Pl.'s Ex. B, TVT Report at 26. Thus, to determine whether a particular mesh product is lightweight or

heavyweight, it is necessary to consider the surface area or volume. Ex. C hereto, 10/02/15 Toglia Dep. 55:16-56:8. For the TTV product, the mesh consists of a 1.1 centimeter strip of material. *Id.* Based on this information, Dr. Toglia opines that it is lightweight mesh.²

Moreover, Dr. Toglia's TTV report includes multiple scientific references supporting his conclusion. Pl's Ex. B, TTV Report at 9-10 (citing Nilsson et al. IUJ 2013; AUGS-SUFU Position Statement on Mesh Midurethral Slings for SUI (2014)); Ex. C hereto, 10/02/15 Toglia Dep. 57:4-22, 332:9-21 (referring to paragraph 1 of the AUGS/SUFU statement describing lightweight monofilament polypropylene sling durability, safety and efficacy including the TTV sling). As this Court previously determined, "the plaintiffs' disagreement with Dr. Toglia's characterization of the terms lightweight and heavyweight does not render Dr. Toglia unqualified to opine on mesh properties; such concerns are better suited for cross-examination." *In re Ethicon*, 2016 WL 4493666, at *3.

There is no merit to Plaintiffs' suggestion that certain references relied upon by Dr. Toglia in his report contradict his opinion. *See* Doc. 2028, p. 7 & n. 44. The reference cited by Plaintiffs, Costello, C.R. (2007), is the sort of case report that Plaintiffs' experts cited which Dr. Toglia had reviewed. Ex. C hereto, 10/02/15 Toglia Dep. 37:9-39:15, 324:11-15. This case report did not involve any of the mesh devices at issue, but instead, large volume hernia mesh. Ex. G hereto. Dr. Toglia repeatedly explained that research involving hernia mesh is lower-level evidence. Pl's Ex. B, TTV Report at 24-26; Ex. C hereto, 10/02/15 Toglia Dep. 325:14-326:6. For comparison purposes, it would be difficult to compare a 1.1 cm strip of TTV mesh to a large mesh sheets, because the volume difference is so large. Pl's Ex. B, TTV Report at 26. Additionally, Dr. Toglia critically analyzes the medical literature and various claims regarding

² Notwithstanding Plaintiffs' characterization of Dr. Toglia's testimony in his Gynemesh PS and Prolift deposition, Dr. Toglia merely explained that "[t]here are no established, universally accepted definitions, cutoffs, consensus of opinion." Ex. B hereto, 3/24/16 Toglia Dep. 115:6-7.

the biocompatibility of the TTV polypropylene mesh in his report. *Id.* at 22-29. Moreover, even if it were the case that contradictory Level 1 evidence existed, such points would be grounds for cross examination, not exclusion.

Finally, Dr. Toglia is well qualified to explain to the jury that the polypropylene MSDS is not reliable for making clinical determinations. Dr. Toglia is not providing a regulatory opinion. He simply intends to explain, as a clinician with expertise in biomaterials, how and why nothing of significance to a pelvic floor surgeon may be gleaned from the MSDS. *See* Ex. C hereto, 10/02/15 Toglia Dep. 239:7-240:10. Just because Dr. Toglia finds the MSDS to be clinically irrelevant does not mean that he is unqualified to testify about its significance to surgeons. This ties into Dr. Toglia's explanation as to why it is prudent to rely on higher levels of evidence (such as Level 1 studies) in formulating clinical opinions, rather than making reckless extrapolations from sources of questionable reliability.

D. The Court should allow Dr. Toglia to testify about the risks and complication rates associated with alternative procedures.

Plaintiffs also challenge Dr. Toglia's qualifications to compare TTV implants with the Burch procedure or autologous slings. Doc. 2028, p. 9. The Court denied this identical challenge in the Wave 1 cases, and it should do so again here. *See In re: Ethicon, Inc.*, 2016 WL 4493666, at *3-4.

Dr. Toglia is a leading expert in the treatment of SUI with extensive experience in a variety of treatment procedures and products, including TTV products, Burch procedures, and autologous sling procedures. Pl's Ex. B, TTV Report at 2; Ex. C hereto, 10/02/15 Toglia Dep. 184-186. He was specifically trained in both the Burch procedure and autologous sling procedures, and has used the procedures in his practice. *Id.* at 217:2-23. Although Dr. Toglia has not performed a Burch or autologous procedure in his practice in several years, he "probably

revises more Burches, fascial slings, bladder neck slings than I do midurethral slings.” *Id.* at 185:4-15. As this Court indicated, Dr. Toglia “does not become unqualified to opine on the relative risks of a group of procedures because he has used his knowledge, experience, and judgment to stop using some of the procedures.” *In re: Ethicon, Inc.*, 2016 WL 4493666, at *3. Under Plaintiffs’ theory, Plaintiffs’ experts who do not use Ethicon’s products are unqualified to testify on this topic.

As the Court further noted, “Dr. Toglia is not relying on personal experience alone; he has engaged in an extensive review of the scientific literature.” *Id.*; *see also* Ex. E hereto, TVT Report Reliance List. Plaintiffs, nevertheless, criticize Dr. Toglia because he could not break down certain Burch complication rates by sub-categories that Plaintiffs’ counsel created during his deposition or cite specific references addressing these sub-categories. *See, e.g.*, Ex. C hereto, 10/02/15 Toglia Dep. 69:12-21. Specifically, in rapid fire succession, Plaintiffs’ counsel asked Dr. Toglia to identify separate rates for sub-categories of suture exposure into the vagina, bladder erosion with a Burch procedure, the incidence of vaginal exposure of suture with a Burch procedure, and urethral exposure with a Burch procedure. *Id.* at 117:1-118:24.

Although Dr. Toglia could not magically produce references addressing the isolated sub-categories of complications identified by Plaintiffs’ counsel, he did refer to scientific literature supporting his opinions about complication and efficacy rates generally. As noted by Dr. Toglia in his deposition, the Schimpf systematic review and meta-analysis is Level 1 data providing information on complications and other problems that can occur with the Burch and the pubovaginal sling. *Id.* at 342:1-23. The study analyzed the number of studies and the incidence of exposure between three different types of midurethral slings: the traditional, pubovaginal and the Burch. *Id.* at 343:10-24. His TVT report further details the various studies that reflect

complication rates in these procedures. PI's Ex. B, TTV Report at 4-5 (citing, *inter alia*, Summit et al. 1992; Beck 1998; Bent 1993; Bryans 1979; Muznai 1992; Mundy 1993; Jarvis 1992);³ TTV Report at 16-18 (comparing published complication rates for Burch and autologous slings with rates experienced in practice).

As set forth in Dr. Toglia's TTV report, exposure, erosion and wound complications occur with the Burch colposuspension and are higher than TTV. *Id.* at 5-6, 19-20, 31-32. Bladder and bowel injury, bleeding, and hematoma, with Burch and TTV occur at similar rates. *Id.* at 31. Consistent with Dr. Toglia's experience, dyspareunia/vaginal pain with TTV is rare and less than that seen with Burch and fascial sling. *Id.* at 19 (citing Schimpf et al., 2014; AUA Updated SUI Guidelines 2012). Moreover, as Dr. Toglia further explained, studies evaluating the complication rates of TTV to traditional incontinence procedures, such as the Burch colposuspension, conclude that the TTV had a lower risk of reoperation than the Burch colposuspension and a similar complication rate compared to pubovaginal sling. *Id.* at 20 (citing Novara et al., 2008).

Dr. Toglia relied upon this published data in forming his opinion, which was "consistent with [his] experience, having performed . . . each of these procedures, and also confirmed [his] experience and [his] own review of the literature of the safety and long-term efficacy" of the TTV procedure. Ex. C hereto, 10/02/15 Toglia Dep. at 344:6-17. Dr. Toglia details the high-level evidence that supports his opinions throughout his expert report. *See, e.g.*, PI's Ex. B, TTV Report at 7-16 (explaining how the literature demonstrates TTV's "slightly higher success rates, better long term durability and less associated morbidity").

In rejecting Plaintiffs' same argument in its Wave 1 ruling, the Court noted that "[t]he Plaintiffs overlook, however, Dr. Toglia's extensive and specific citation to scientific studies in

³ Copies of these and any other literature referenced in this brief may be provided upon request.

his report,” and that “Dr. Toglia’s failure to identify, on the spot, a study to support a very specific sub-issue is not enough to undermine the reliability of his methodology as demonstrated in his expert report.” *In re: Ethicon, Inc.*, 2016 WL 4493666, at *4; *see also Tyree*, 54 F. Supp. 3d at 522 (finding that a physician’s inability to identify direct comparison studies of the Burch procedure and the use of slings during his deposition did not make his opinions regarding the efficacy of Burch procedure unreliable).

E. Dr. Toglia’s opinions regarding degradation and immune response are grounded in extensive clinical experience reinforced by scientific literature.

Noting that “sub-specialty societies such as AUGS and SUFU have dismissed [concerns about alleged degradation] by pointing out that they are not supported by extensive peer reviewed literature,” Dr. Toglia states in his TVT report that “my analysis of the data, including the numerous long term studies on TVT referenced in this report, leads me to conclude that the Prolene polypropylene in TVT does not degrade.” Pl’s Ex. B, TVT Report at 28; Ex. E hereto, Reliance List. Dr. Toglia has also stated that this opinion is also based on his vast personal experience and that, even if mesh degrades, it is clinically insignificant. *Id.*; Ex. C hereto, 10/02/15 Toglia Dep. 135:9-13, 151:22-152:5. Plaintiffs make a feeble attempt to suggest that these opinions lack a reliable methodology and that Dr. Toglia struggled during his deposition to cite studies supporting his opinions. *See* Doc. 2028, p. 10.

The Court may readily reject Plaintiffs’ argument for the same reasons that it rejected this identical argument in its Wave 1 ruling. As noted by the Court:

Dr. Toglia’s difficulty naming studies on the spot during a deposition does not necessarily negate the studies and reasons articulated in his expert report. In his report, Dr. Toglia makes general reference to studies, meta-analyses, and systematic reviews; he also specifically cites several studies and explains that the studies are consistent with his own personal observations. The plaintiffs’ objection addresses the weight, rather than the admissibility, of the opinion.

Accordingly, to the extent the plaintiffs seek to exclude Dr. Toglia's opinions on immunologic response, their motion is **DENIED**.

In re: Ethicon, Inc., 2016 WL 4493666, at *4.

Indeed, in forming his opinions, Dr. Toglia analyzed many scientific articles, which he found consistent with his extensive clinical experience. Pl's Ex. B, TTV Report at 28; Ex. E hereto, Reliance List; Ex. C hereto, 10/02/15 Toglia Dep. 151:22-152:5, 344:6-17. As he has repeatedly testified, "there is no high-quality evidence that suggests that polypropylene degrades in the body." *Id.* at 133:23-134:1.⁴ Any suggestion that mesh degrades in the body is "inconsistent with the body of Level 1 evidence and the long-term registration studies." *Id.* at 134:14-22. According to Dr. Toglia, "[t]here are no clinical concerns that that phenomenon exists." *Id.* at 135:8-13.⁵

Plaintiffs' hollow argument that Dr. Toglia cannot support his degradation opinions ignores Dr. Toglia's expert report, as well as the evidence he identified at his deposition. First, the lack of Level 1 evidence supporting a finding of clinical degradation is scientifically significant and compelling in light of the fact that mesh has been used *in vivo* for decades and is

⁴ In practice, Dr. Toglia routinely sends mesh specimens to the lab for identification. *Id.* at 210:13-21. Although he does not look at the slides under a microscope himself, he is familiar with what microscopic examinations of mesh look like. *Id.* at 211:2-9. He has studied them in scientific articles, which include "clear photomicrographs ... with accurate pathologic descriptions" and stated that he has "an excellent working knowledge of these topics." *Id.*; Ex. C hereto, 10/02/15 Toglia Dep. 262:21-263:15. *See also* Tyree, 54 F. Supp. 3d at 585 (simply because physician has not personally performed pathology research on polypropylene explants does not render him unqualified to testify regarding mesh shrinkage, contraction, degradation, or propensity to cause infection).

⁵ Plaintiffs' attempts to distinguish the Falconer study during the deposition and their brief (Doc. 2028, p. 10) provide nothing more than grounds for cross-examination. Thwarted by Dr. Toglia's ability to effectively support his opinion regarding degradation, Plaintiffs' counsel proceeded to question him regarding sub-categories of degradation that Plaintiffs' counsel could not even define to form a proper question. When Dr. Toglia explained that Falconer (2011) indeed supported the conclusion that there was no clinically significant degradation of the mesh, Plaintiffs' counsel proceeded by limiting her questions to "chemical degradation" asking Dr. Toglia if he was "aware of any studies, then that demonstrate that chemical degradation does not occur." *Id.* at 139:23-140:2. When asked by Dr. Toglia to clarify the meaning of "chemical degradation" --whether it was directed at "isomeric change in the compound" or "racemic change" or "nephelation of the compound" -- Plaintiffs' counsel could not, and changed the direction of the questioning. *Id.* 141:1-142:1.

the “most extensively studied anti-incontinence procedure in history.” Pl’s Ex. B, TTV Report at 31; Ex. C hereto, 10/02/15 Toglia Dep. 331:19-22.

Moreover, Dr. Toglia specifically referred to a 2001 study by Falconer that tested site-specific biopsies that demonstrated no structural degradation into the tissue surrounding implanted mesh. Ex. C hereto, 10/02/15 Toglia Dep. 137:4-8; Ex. H hereto, Falconer (2001). As he further explained, “[w]ithin the clinical use of the TTV for the treatment of stress urinary incontinence, there – I’m not aware of any reliable data suggesting that there is degradation.” Ex. C hereto, 10/02/15 Toglia Dep. 345:13-22.

Furthermore, Dr. Toglia adequately explained his rejection of literature cited by Plaintiffs as purportedly providing evidence of degradation. Specifically, counsel questioned Dr. Toglia regarding the Clave 2010 study, which, as Dr. Toglia opined, “would not be considered in that kind of high-level evidence analysis, in terms of clinical utility, safety or design of that device.” *Id.* at 347:7-19. Dr. Toglia addressed the design limitations of the study, noting that it offered mere “hypotheses” regarding in vivo degradation. *Id.* at 348:17-349:5. He provided a lengthy explanation of why the study did not, and cannot, support the conclusion that degradation in vivo occurs. *Id.* at 347-352 (“[Y]ou simply can’t infer. You can’t clinically infer from a paper such as this, which is just sort of an observation to any kind of effect that it might have when it’s used for its typical indication.”). Indeed, the authors admitted that specific deteriorations correlating to implant material were not observed, and that they further acknowledge that they were unable to confirm their hypothesis concerning potential degradation, and that they were unable to determine whether the mechanical properties were altered. Pl’s Ex. B, TTV Report at 28. Thus, Dr. Toglia’s opinions about degradation are based on sound methodology.

Plaintiffs' criticisms of Dr. Toglia's opinions regarding immunologic response/foreign body reaction are similarly unfounded. Dr. Toglia repeatedly demonstrated in his testimony that the "long-term Level 1 evidence studies speak to the lack of a significant immune response." *Ex. C* hereto, 10/02/15 Toglia Dep. 197:16-19. This evidence includes, "consistent with what is stated by the FDA, what is stated by NICE, what is stated by AUA, AUGS, and SUFU, that there is – that polypropylene mesh, macroporous, as used with the TVT device for its intended purpose, is the most biomechanic – biocompatible material. By definition, biocompatible speaks to host tolerance and the lack of immunologic response." *Id.* at 198:3-14.

Again, this scientific evidence is also consistent with Dr. Toglia's clinical experience. Out of 3,000 patients in which he has implanted polypropylene mesh, he has not observed one single clinical chronic foreign body reaction. *Id.* at 202:2-17, 206:14-207:11, 151:22-152:5. Dr. Toglia, who has encountered foreign body reaction with other implant material and is "very familiar with the presentation," also explained the clinical symptoms that would indicate chronic foreign body reaction. *Id.* at 202:11-203:6. His experience is "consistent with the long-term registries trials . . . that focused on the safety and looked specifically for that kind of problem." *Id.* at 151:22-152:9 (counsel statements omitted).

In fact, Dr. Toglia has published on the clinical presentations as it relates to chronic granulomatous response to a foreign body within the context of reconstructive pelvic surgery. *Id.* at 203:3-14.⁶ When afforded the opportunity on cross-examination, he explained his rejection of low-level evidence that Plaintiffs suggested contradicted his conclusions. *Id.* at 353:2-354:6. Dr. Toglia noted that, in examining the literature, one must distinguish between "reactions that the body has that are of no clinical consequence, [and] reactions that the body has that could

⁶ Although Plaintiffs' counsel continually attempted to question Dr. Toglia about non-symptomatic reaction to implanted material, Dr. Toglia thoroughly explained why such reaction is not clinically significant. *See, e.g., id.* at 205:5-206:13.

result in an adverse clinical outcome.” *Id.* at 354:1-6. In evaluating Dr. Toglia’s testimony, the court “must not concern [it]self with the ‘correctness of the expert’s conclusions’ and should instead focus on the ‘soundness of his methodology.’” *Id.* (citations omitted). Any alleged inconsistencies or weaknesses in Dr. Toglia’s testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence”).

Unlike other cases this Court has addressed, this is not a situation where there is “insufficient investigation and information to come to a conclusive determination.” *See Tyree*, 54 F. Supp. 3d at 584 (rejecting expert testimony regarding adequacy of warnings that relied upon the fact that the expert simply had not personally observed certain alleged risks). Here, not only has Dr. Toglia not personally observed the risks Plaintiffs identify, he has performed an exhaustive review of the medical literature that spans decades on this particular product and has concluded, based on his expertise, that there is no reliable evidence substantiating Plaintiffs’ claims. And, he also specifically explains his rejection of contrary claims in the literature relied upon by Plaintiffs’ experts. This is sound methodology, and on multiple occasions, this Court has rejected similar arguments made by Plaintiffs and determined that a clinician expert may reliably base opinions that mesh does not degrade on the expert’s clinical experience and his review of scientific literature. *See, e.g., Huskey*, 29 F. Supp. 3d at 734-35; *Carlson*, 2015 WL 1931311 at *12.⁷

F. The Court should allow Dr. Toglia to offer opinions about warnings.

⁷ Finally, and in the alternative, even if Dr. Toglia were not competent to testify that TVT polypropylene mesh does not degrade, he is still well qualified to testify that there is no reliable evidence that the mesh degrades and to explain to the jury why the foundation for Plaintiffs’ experts’ opinions of degradation is unreliable. Opining that mesh does not degrade is altogether different than opining that there is no reliable evidence that mesh degrades or that there is no reliable evidence that any degradation has clinical significance.

Dr. Toglia has opined on the completeness and accuracy of the IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Pl's Ex. B, TVT Report at 3, 32. Plaintiffs do not challenge, or even address, Dr. Toglia's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the IFUs because he is not a warnings expert.

Ethicon concedes that Dr. Toglia is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings, however, Dr. Toglia, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon*, 2016 WL 4493666, at *4. Dr. Toglia's reports and deposition testimony detail his extensive experience with the devices, including particular risks and complications he has experienced and researched, and as reflected over pages of testimony, Dr. Toglia explained why each of the IFU disclosures was accurate based on both his experience and the Level 1 information relevant to the product. Ex. C hereto, 10/02/15 Toglia Dep. 272-291.

As this Court determined in its Wave 1 ruling, Plaintiffs do not appear to challenge Dr. Toglia's competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians. *See In re: Ethicon*, 2016 WL 4493666, at *7 n. 2. To the extent that their motion is construed as doing so, any such challenge should be denied. Dr. Toglia will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Toglia's report and deposition show that his opinions are based on his extensive clinical experience, *as well as* his thorough critique of

scientific literature. *See, e.g.*, Pl's Ex. B, TTV Report at 19-28 (explaining why he disputes that mesh causes various conditions, such as particle loss, sarcomas, or degradation). *See also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12.⁸

Dr. Toglia, as an experienced clinician, is well qualified to testify about risks that are obvious to surgeons “in light of our education, training and experience.” Pl's Ex. B, TTV Report at 17, 32. *See also id.* at 16-17 (discussing at length ordinary complications associated with SUI surgery, such as injury to vessels, infection, bleeding, scarring, voiding problems, erosion, and the need to reoperation, which are “elemental” to surgeons and need not be included in the IFU). Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants’ experts as to what “is known within the correctional medical community”); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of “common knowledge”); *U.S. v. Articles of Device*, 426 F.Supp. 366 (W.D.Pa. 1977) (FDA offered affidavit in misbranding case).

Dr. Toglia detailed in his report the level of knowledge that would be expected of any surgeon performing pelvic floor surgery and reviewing the IFU, noting that “most surgical risks are common to anti-incontinence procedures as a group.” *Id.* at 16-17 (citing Chahila 1999;

⁸ While this Court has observed that “[a]bsence of evidence is not evidence of absence,” *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician’s opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

AUA SUI Guideline 2012; AUA 2013 Position Statement; Schimpf et al, 2014). The TVT IFU supplements all the other sources of a surgeon’s knowledge. *Id.* Thus, as Dr. Toglia has opined, the “IFU and Professional education for the TVT are clear, useful and adequate to describe the procedure and potential risks.” *Id.*

The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if “the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.”

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Toglia is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Toglia. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon’s IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

Finally, Plaintiffs’ other criticisms of Dr. Toglia’s warnings opinions rely upon isolated statements that are taken out of context. Doc. 2028, pp. 11-12. For instance, it is true that Dr. Toglia testified that he would not rely on Ethicon to provide him with information regarding the

risks associated with the TVT device. However, as Dr. Toglia explained, he does not rely on information provided by Ethicon because it is not Level 1 evidence, and he instead relies upon his own research and experience. *See, e.g.*, Ex. C hereto, 10/02/15 Toglia Dep. 178:17-21.

Similarly, although Dr. Toglia stated that he did not know what Plaintiffs' counsel meant by "complete" when counsel asked if the IFU was "complete and accurate" regarding the potential risks, it is apparent that, in text, Dr. Toglia was simply asking counsel to clarify the question so that he could understand whether he was being asked to comment on potential updates that had occurred or that might occur. *Id.* at 280:10-20. Plaintiffs also questioned Dr. Toglia about what a particular physician or patient would "want to know," to which Dr. Toglia accurately responded that he could not speak to what a particular doctor might consider relevant or would want to know. *Id.* at 269:16-17.

CONCLUSION

For the reasons stated herein, the Court should deny Plaintiffs' motion to limit Dr. Toglia's testimony.

Respectfully Submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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